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Throughout the United States, escalating drug prices are putting immense pressure on state budgets. Several states are looking for ways to push back. Last year, Massachusetts asked the Trump administration for a waiver that would, among other things, allow its Medicaid program to decline to cover costly drugs for which there is limited or inadequate evidence of clinical efficacy.[1] By credibly threatening to exclude such drugs from coverage, Massachusetts hoped to extract price concessions and constrain the fastest-growing part of its Medicaid budget.

In late June, however, the Centers for Medicare and Medicaid Services (CMS) denied Massachusetts' request.[2] On the same day, the agency issued a memorandum clarifying that, under requirements included in the Omnibus Budget Reconciliation Act of 1990, state Medicaid programs are legally obliged to cover all drugs approved by the Food and Drug Administration (FDA) — including those approved under the agency's less rigorous accelerated-approval pathway.[3]

Many of these drugs — including some with uncertain efficacy — are very expensive. Take, for example, Exondys 51 (eteplirsen), which was approved for the treatment of Duchenne's muscular dystrophy on the basis of a trial that involved 12 boys and used a surrogate end point. The drug's label states that "a clinical benefit of Exondys 51 has not been established," yet the retail price of the drug is about $300,000 per year. State Medicaid programs don't pay full price — that same 1990 legislation entitles them to a discount that today amounts to at least 23% of the drug's average sales price. Even so, drugs like Exondys 51 are straining state budgets.

To reduce the burden of high-cost, low-value drugs, Massachusetts has proposed establishing a closed formulary, in which certain drugs can be excluded from coverage. The Trump administration might have been expected to welcome the proposal. At least rhetorically, it is committed to reducing drug prices. And closed formularies are ubiquitous in private insurance and public health care programs alike. The Veterans Health Administration uses one, and Medicare Part D plans can exclude certain products.

So why not let Massachusetts try a closed formulary for Medicaid? CMS's letter to the state doesn't say. It is silent on what exactly is deficient about Massachusetts' request. The letter does claim that CMS "would be willing to consider" a closed formulary — but only if Massachusetts both gives up the steep discounts that it's entitled to by law and demonstrates that its Medicaid spending won't increase because of the changes.

Together, these requirements create an insuperable obstacle to any closed formulary. Under CMS's

proposed terms, Massachusetts would be required to bargain with manufacturers for every covered drug, without the existing price discounts guaranteed by law. That isn't practical. No state would surrender the automatic discounts that it gets on all drugs just so it can drive a harder bargain over the few FDA-approved drugs that it might exclude from coverage. Furthermore, state Medicaid agencies work under tight budget constraints, and they lack the resources and personnel to conduct individual negotiations for every covered drug.

Requiring states to demonstrate budget neutrality exacerbates the problem. It is difficult to see how a state could negotiate substantial enough discounts on individual drugs to make up for the loss of mandatory price discounts. Any state desperate enough to try would probably have to place substantial restrictions on access to clearly effective drugs,[4] which would be unacceptable in a safety-net program. CMS's proposed alternative might also undo patients' legal entitlement to needed drugs, thus depriving them of their ability to sue states over any access restrictions.

In any event, it is not sufficient for CMS to describe a waiver that it would approve; it must explain why it rejected the waiver that Massachusetts requested. For example, the agency could have said — but didn't — that the waiver is bad policy. It could have said — but didn't — that the waiver contravenes the purposes of the Medicaid statute. It could have said — but didn't — that the agency lacks the resources to oversee a novel waiver like this one. CMS offered no explanation at all for the rejection. It didn't even say why its proposed alternative is superior to what Massachusetts requested.

From a legal perspective, that's a problem. Administrative law requires agencies to provide reasons for their actions. Judges will usually defer to those reasons, but an unexplained action won't stand up in court. If Massachusetts sues, the agency's decision is at least as vulnerable as other actions that judges have recently invalidated, including CMS's approval of Kentucky's Medicaid work requirement. Indeed, CMS's willingness to push the legal envelope on work requirements stands in stark contrast to its timidity when it comes to Massachusetts' request to experiment with a closed formulary.

In recent public statements, officials from the Department of Health and Human Services (HHS) have suggested new explanations for the decision to deny Massachusetts' request. CMS Administrator Seema Verma asserted that the request was not legally permitted but did not explain why. HHS Secretary Alex Azar argued in the *New York Times* that Massachusetts' attempt to exclude some drugs from coverage while retaining the mandatory discounts "render[ed] the proposal an attempt at double-dipping."

These after-the-fact justifications track an argument that the pharmaceutical industry pressed in its campaign against the Massachusetts waiver. In its view, the establishment of a closed formulary would violate a "grand bargain" it struck with Congress as part of the 1990 legislation.[5] The industry's view of that bargain is that it agreed to sell drugs to Medicaid programs at a discount, and, in exchange, states would have to cover every FDA-approved drug.

Azar and Verma appear to believe that departing from the law's purportedly neutral baseline would be unlawful, unfair, or both. But no part of the 1990 law limits CMS's waiver authority over the portion of the Medicaid statute that governs prescription drugs. That's an important omission. Congress knows how to restrict the scope of waivers when it wants to; indeed, it has done so in other parts of the Medicaid statute (for example, under the section covering cost-sharing requirements). For its part, CMS recently granted Oklahoma's request to waive a different part of the same statutory provision that Massachusetts now seeks to waive, suggesting that the agency's legal objections are a pretext.

What's more, the grand bargain has already been violated — but not by Massachusetts. Since 1990, changes in pricing strategies, the proliferation of orphan drugs and complex biologics, and the decreasing rigor of the FDA approval process have placed an enormous strain on state Medicaid budgets. Massachusetts' request reflects a thoughtful effort to restore the balance established by that bargain in light of an evolving pharmaceutical market. In rejecting the request, the Trump administration appears to have sided with the drug industry over the states.

Disclosure forms provided by the authors are available at NEJM.org.

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